

## TOP 10 THINGS YOU NEED TO KNOW WHEN OPERATING A PHARMACY

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    - **Please note:** This course is accepted by the Texas State Board of Pharmacy for both general credit and as fulfilling the law requirement. *However, it is NOT ACPE certified and will not appear in your CPE Monitor account.*




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## TOP 10 THINGS YOU NEED TO KNOW WHEN OPERATING A PHARMACY

Allison Vordenbaumen Benz, R.Ph., M.S.  
Director of Professional Services  
June 22, 2016




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## Goals

- Discuss important requirements for operating a pharmacy;
- Review the most common Warning Notices Issued to Pharmacies;
- Review pharmacy related legislation passed by the 2015 Legislature; and
- Review some current issues facing the Board.




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### Board of Pharmacy Members

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TEXAS STATE BOARD OF PHARMACY



### TSBP Mission

- To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas, through the regulation of the practice of pharmacy; the operation of pharmacies; and the distribution of prescription drugs in the public interest.



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TEXAS STATE BOARD OF PHARMACY

## The Top Ten




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### Number 10

- Insurer's providing professional liability insurance to pharmacists, pharmacy technicians, or a pharmacy license holder must provide the Board information regarding a notice of claim or complaint filed against an insured in a court.




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### Number 10

- If the pharmacist, pharmacy technician, or pharmacy is self insured, the duty to report this information is the responsibility of the pharmacist, pharmacy technician or pharmacy license holder.
- <http://www.pharmacy.texas.gov/about/liabilityform.asp>




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### Number 9

- The theft/significant loss of any controlled substance by a pharmacy must be reported in writing to the Board immediately upon discovery. This information may be submitted on a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.




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### Number 9

- In addition, a pharmacy shall report in writing to the Board immediately upon discovery, the theft or significant loss of any dangerous (non-controlled) drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.
- Board rule 291.3




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### Number 8

- When a change of PIC of a pharmacy occurs, the required inventory must be taken on the date of the change.
- The PIC must notify the Board that a change of PIC has occurred and that the inventory was taken.
- This information must be reported to the Board within 10 days.
- Board rules 291.3, 291.17




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### Number 7

- When a pharmacy closes, the pharmacist-in-charge shall forward to the Board, within 10 days, the following items:
  - written notice of the closing which includes the actual date of closing;
  - pharmacy license;




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### Number 7

- statement attesting that the required inventory has been conducted and the manner by which the drugs possessed by the pharmacy were transferred or disposed; and
- location of all records belonging to the pharmacy (e.g., if prescription records were transferred to another pharmacy, give name and address of pharmacy).

- Board rule 291.5




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### Number 6

- When a pharmacy changes ownership, a new pharmacy application must be filed with the Board and the license issued to the previous owner shall be returned to the Board.
- Board rule 291.1




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### Number 5

- When a pharmacy changes location, a new pharmacy application must be filed with the Board no later than 30 days before the change.
- Disasters, accidents, and emergencies which require the pharmacy to change locations shall be immediately reported to the Board.
- Board rule 291.3



TEXAS STATE BOARD OF PHARMACY

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### Number 4

- Inventories must be filed separately from all other records in the pharmacy and be available for inspection for 2 years.



TEXAS STATE BOARD OF PHARMACY

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### Number 3

- An annual inventory must be taken on May 1 of each year or on the pharmacy's general physical inventory date.
- The inventory may be taken within 4 days of the specified inventory date and must include all controlled substances.
- The inventory must be signed by the PIC and notarized within 3 working days of completing the inventory.



TEXAS STATE BOARD OF PHARMACY

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## Number 2

- The pharmacist-in-charge (PIC) is responsible for taking an initial inventory on the opening day of business; however, the PIC may delegate this to another individual.
- The inventory must include all controlled substances.
- Board rule 291.17



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## Number 1

- A pharmacy must open and be in operation with a sufficient number of transactions within 6 months of the date of issuance of the pharmacy's license.
- Board rule 291.11



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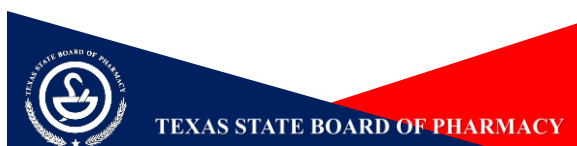
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## Conditions Receiving "Warning Notices" FY2015



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## Number of Inspections

Class	FY2015	% of FY2015 Inspections
Class A Pharmacies	2,275	76%
Class A-S	144	5%
Class B Pharmacies	5	<1%
Class C Pharmacies	268	9%
Class C-S	128	4%
Class D Pharmacies	95	3%
Class F Pharmacies	61	2%
Class G Pharmacies	15	<1%
Totals	2,991	100%

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## Warning Notices

Class	# Pharmacies Receiving WN	% Receiving WN
Class A	992	77%
Class A-S	84	6%
Class B	2	<1%
Class C	80	6%
Class C-S	87	7%
Class D	31	2%
Class F	17	1%
Class G	0	N/A
Totals	1,293	100%

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## Most Common Warning Notices (All Classes of Pharmacy)

Violation	Number of WN Issued*
Records	731
Sterile Preparations	647
Pharmacy Technicians	564
Drug/Stock Environment	421
Prescriptions	335
Inventory	319
* One pharmacy may receive multiple Warning Notice violations.	

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**Most Common Warning Notices  
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
<b>Records</b>		<b>731</b>
Records Not Available	314	
Absence of R.Ph. Record	66	
Rx Not Separated	17	
Rx Records Not Numerical Order	25	
Improper Transfer of RX copies	3	
Invoices Not Separated/Retrievable	122	
Records for Non-Sterile Compounds	169	
No Written Information on RX	10	

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**Most Common Warning Notices  
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
<b>Sterile Preparations</b>		<b>647</b>
No/Incomplete QA/QC	99	
No/Incomplete P&P Manual	237	
No/Inadequate Preparation Area	165	
IV Preparation	131	
No DUR	13	
Cytotoxic/Bio Procedures	2	

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**Most Common Warning Notices  
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
<b>Pharmacy Technicians</b>		<b>564</b>
No/Incomplete Training	510	
No/Improper Supervision	19	
Improper Registration	29	
No Name Tags	6	

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**Most Common Warning Notices  
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
Drug Stock/Environment		421
Improper Environment	137	
Out-of-Date Drug Stock	158	
Security	65	
Unsanitary	32	
Improper Drug Storage	20	
Area for Non-Sterile Compounding	7	
Violation of Limited Formulary	2	

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**Most Common Warning Notices  
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
Prescriptions		335
Lack Proper Information	159	
Prescription Label Incorrect	136	
Official Rx Non-Compliance	40	

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**Most Common Warning Notices  
(All Classes of Pharmacy) cont.**

Condition	Number of WN Issued	Total
Inventory		319
No Annual Inventory	84	
No Change of Ownership Inventory	5	
No Change of PIC Inventory	35	
Incomplete Inventory	194	
Improper Drug Destruction	1	

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### Violations NOT Resulting in Warning Notices

- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.




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### Violations NOT Resulting in Warning Notices

- Pharmacy is not able to produce 2 consecutive annual inventories.
- PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).




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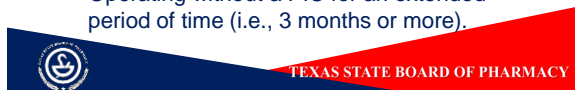
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### Violations NOT Resulting in Warning Notices

- Egregious Conditions
  - Dispensing CII's pursuant to prescriptions not issued on an Official Form;
  - Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
  - Pharmacy closed and did not notify TSBP of closing;
  - Operating without a PIC for an extended period of time (i.e., 3 months or more).




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### Violations NOT Resulting in Warning Notices

- Continuing threat – For example:
  - Impaired pharmacist on duty; or
  - Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to “*cease and desist*” sterile compounding until conditions have been corrected.
- Both of these scenarios would result in an Emergency Temporary Suspension Hearing.




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### Pharmacy Related Legislation Passed by the 2015 Legislature




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### S.B. 195 by Sen. Schwertner

- This bill:
- Moves the Prescription Monitoring Program from the Department of Public Safety (DPS) to the Board of Pharmacy; and
- Eliminates the Texas Controlled Substance Registration program.




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## Timeline for Transfer of the PMP Program

- **November 2015** – RFP for the new PMP issued by TSBP.
- **January 2016** – Appriss selected as the vendor.
- **February – May 2016** – System installation at TSBP.
- **May/June 2016** – Testing of program.
- **September 1, 2016** – NEW PMP goes live.




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Request Patient Rx Report
3 of 7

[Go Back](#)
[User Profile](#)
[Help](#)
PMP AWARE

[Go Back](#)
[Patient Request](#)
[Request History](#)
[MyRx](#)

### Patient Request

[Rx Patient Request Tutorial](#)

**Patient Info**
First Name\*  
Last Name\*  
DOB\*  
mm/dd/yyyy  
Phone Number  
Social Security Number  
Drivers License Number

**Patient Location**
City  
State/Province  
State Select  
Zip Code

**PMP Interconnect Search**
☐ Colorado PMP  
☐ Illinois  
☐ Nevada  
☐ New Jersey Test  
☐ North Dakota  
☐ Oklahoma  
☐ South Carolina  
☐ Utah PMP

**Prescription Fill Dates**
From\*  
02/26/2014  
To\*  
02/26/2015

**Search for a Patient**

- Required fields are indicated by a red Asterisk \*
- At a minimum, First Name, Last Name, and DOB are required.
- Including additional information, such as Zip Code, can improve your search.

[Back](#)
[Next](#)

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Request Patient Rx Report
4 of 7

[Go Back](#)
[User Profile](#)
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PMP AWARE

[Go Back](#)
[Patient Request](#)
[Request History](#)
[MyRx](#)

### Patient Request

[Rx Patient Request Tutorial](#)

**Patient Info**
First Name\*  
Last Name\*  
DOB\*  
mm/dd/yyyy  
Phone Number  
Social Security Number  
Drivers License Number

**Patient Location**
City  
State/Province  
State Select  
Zip Code

**PMP Interconnect Search**
☐ Colorado PMP  
☐ Illinois  
☐ Nevada  
☐ New Jersey Test  
☐ North Dakota  
☐ Oklahoma  
☐ South Carolina  
☐ Utah PMP

**Prescription Fill Dates**
From\*  
02/26/2014  
To\*  
02/26/2015

**Search for a Patient**

The Prescription Fill Dates default to a search period of 1 year from the current date, but can be adjusted to search a different time frame.

[Back](#)
[Next](#)

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Request Patient Rx Report
5 of 7

[Go Back](#)
[User Profile](#)
[Help](#)
PMP AWARE

[Go Back](#)
[Patient Request](#)
[Request History](#)
[MyRx](#)

### Patient Request

[Rx Patient Request Tutorial](#)

**Patient Info**
First Name\*  
Last Name\*  
DOB\*  
mm/dd/yyyy  
Phone Number  
Social Security Number  
Drivers License Number

**Patient Location**
City  
State/Province  
State Select  
Zip Code

**PMP Interconnect Search**
☐ Colorado PMP  
☐ Illinois  
☐ Nevada  
☐ New Jersey Test  
☐ North Dakota  
☐ Oklahoma  
☐ South Carolina  
☐ Utah PMP

**Prescription Fill Dates**
From\*  
02/26/2014  
To\*  
02/26/2015

☐ I agree to the terms of the acknowledgement.

[Search](#)

**Access other PMP Interconnect States**

If you wish to search other states for information about this patient, check the corresponding box next to any state available under the PMP Interconnect Search section. Once all information you wish to enter about the patient has been entered, simply agree to the terms and click search.

[Back](#)
[Next](#)

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## H. B. 1550 by Zerwas/Kolkhorst (cont.)

- This bill amends the Pharmacy Act to:
  - Specify a pharmacist:
    - May not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.
    - Who administers epinephrine through an auto-injector device is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.




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## Current Issues




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## Sunset Review

- Texas Pharmacy Act, Sec. 551.005.  
Application of Sunset Act.
  - The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September 1, 2017.




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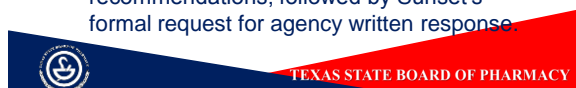
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## Sunset Review Time Line

- August 2015.
  - TSBP prepares a Self-Evaluation Report.
- October 2015 – March 2016.
  - Sunset staff reviews the agency.
- Late March 2016.
  - Sunset’s confidential report issued followed by a joint meeting with TSBP to discuss recommendations, followed by Sunset’s formal request for agency written response.




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## Sunset Review Time Line (cont.)

- April 2016.
  - Sunset staff report published.
- June 23, 2016.
  - Sunset Commission holds a public hearing to receive public comment on the agency.
- Summer 2016.
  - Commission decisions are issued.
- January – May 2017.
  - 2017 Legislative Session




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**TSBP Website**  
[www.pharmacy.texas.gov](http://www.pharmacy.texas.gov)




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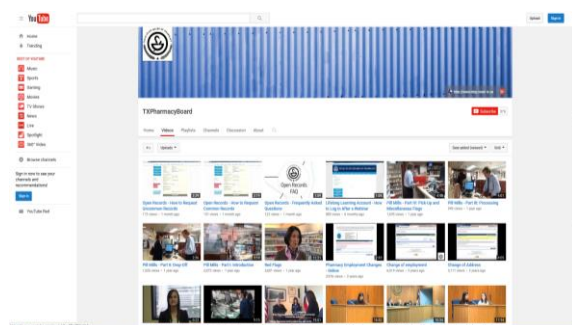
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## Final Reminders

- **Receiving Credit**
  - Look for the quiz and evaluation to be posted in your Lifelong Learning Account 5-7 days from now
    - An email notification will be sent to you when these are available
  - **You will have 30 days from the date they are posted to complete them.**
  - Complete these items to generate your certificate, which can be accessed at any time through your Lifelong Learning Account.
    - Trouble accessing your Lifelong Learning Account?**
    - Questions about your attendance?**
    - Call the help desk:**
    - 1-800-215-0641**
    - Select Option 1**

**Please note:** This course is accepted by the Texas State Board of Pharmacy for both general credit and as fulfilling the law requirement. **However, it is NOT ACPE certified and will not appear in your CPE Monitor account.**




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## Thank You!

Thank you for your attendance!

If you have additional compliance-related questions, please call the  
TSBP Compliance Line at 512-305-8070.

For questions about today's presentation, please email us at:

[educationcoordinator@pharmacy.texas.gov](mailto:educationcoordinator@pharmacy.texas.gov)



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